

Misbranding, Section 502 (j) the *dextrose injection* was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, "Note: The contents are for use at one time * * * Directions: Administer slowly intravenously."

DISPOSITION: September 6, 1946. Pleas of guilty having been entered, the court imposed a fine of \$500 against the defendants, jointly, on each of the 3 counts of the information.

DRUGS ACTIONABLE-BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2102. Misbranding of Pronto-Lax, Mineral Crystals, Famous Residuum, Nose Spraying Solution, and Eye Bath. U. S. v. Famous Mineral Water Co. and Howard Nevils. Pleas of guilty. Fine of \$100 against each defendant on count 1; fine of \$500 generally, but suspended for 3 years, against the defendants on the other counts of the information. (F. D. C. No. 20169. Sample Nos. 21861-H to 21865-H, incl.)

INFORMATION FILED: September 18, 1946, Northern District of Texas, against the Famous Mineral Water Co., a corporation, Mineral Wells, Tex., and Howard Nevils, secretary and treasurer of the corporation.

ALLEGED SHIPMENT: From the State of Texas into the State of Tennessee. The products were shipped on or about January 14 and April 3, 1945, and a number of circulars entitled "Dismuke's Famous Mineral Water" and "The Original and Genuine Famous Mineral Crystals" were shipped during December 1944.

PRODUCT: Analyses disclosed that the *Pronto-Lax* was an alkaline mineral water containing chiefly sodium sulfate (Glauber's salt) and sodium chloride (common table salt); that the *Mineral Crystals* was a partially crystallized sodium sulfate containing small amounts of sodium chloride and sodium carbonate; that the *Famous Residuum* was a concentrated mineral water containing mainly sodium chloride, sulfate, and carbonate, with some sodium nitrite; that the *Nose Spraying Solution* was a mineral water containing mainly sodium chloride, sulfate, and carbonate, with some sodium nitrate; and that the *Eye Bath* was essentially of the same composition as the *Nose Spraying Solution*.

LABEL, IN PART: "Dismuke's Pronto-Lax Concentrated Famous Mineral Well Water," "Dismuke's Famous Mineral Crystals," "Famous Residuum Made From The Crystals of the Famous Mineral Well Water," "Dismuke's Nose Spraying Solution," or "Dismuke's Eye Bath."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the respective products were false and misleading since the articles would not be effective to accomplish the purposes represented and suggested. The following false and misleading representations were made for the articles in the labeling:

That the *Pronto-Lax* was a tonic; that it would eliminate toxic poisons from the system, which poisons cause the majority of human ailments, and would eliminate poisons in a natural manner; that it would be beneficial to the stomach, kidneys, and liver; that it was life-saving, and would help suffering humanity; that it would make the user a "new man," and would keep the user in good health; and that it would improve digestion, and would be efficacious in the cure, mitigation, treatment, and prevention of diabetes, enlarged liver, carbuncle, mucous colitis, stomach trouble, ulcerated stomach, colon trouble, sciatica, rheumatism, hives, and autointoxication.

That the *Mineral Crystals* would be efficacious in the cure, mitigation, treatment, and prevention of acid stomach, colds, headaches, biliousness, indigestion, bad complexion, rheumatism, arthritis, neuritis, high blood pressure, and diabetes; that it would purify the system; that it would be beneficial after excessive eating and drinking; that it would enable the user to get well; and that it would eliminate toxic poison in the system.

That the *Famous Residuum* possessed tonic and healing properties, and would be efficacious in the cure, mitigation, treatment, and prevention of cuts, burns, insect bites, eczema, rash, poison ivy, acid stomach, acute indigestion, stomach trouble, ulcerated stomach, colic, and similar troubles; that it would enable the user to breathe normally and sleep soundly; and that it would tone up the digestive tract and prolong life,

That the *Nose Spraying Solution* would be efficacious in the cure, mitigation, treatment, and prevention of head colds, hay fever, sinus, and catarrhal trouble.

That the *Eye Bath* possessed healing properties, and was an antiseptic; and that it would be efficacious in the cure, mitigation, treatment, and prevention of eye strain, blue, granulated lids, and sore eyes.

Further misbranding, Section 502 (a), the labeling of the *Pronto-Lax* was false and misleading since it represented and suggested that the article contained healing minerals, and that it was recommended by the Food and Drug Administration as the greatest mineral water in the world. The article did not contain healing minerals, and was not recommended by the Food and Drug Administration.

Misbranding Section 502 (f) (2), the *Pronto-Lax* and *Mineral Crystals* were laxatives; and their labeling failed to warn that they should not be used in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the articles might result in dependence upon laxatives to move the bowels.

DISPOSITION: November 12, 1946. Pleas of guilty having been entered, the court imposed a fine of \$100 against each individual on count 1 of the information, which related to the *Pronto-Lax*. The court imposed also a fine of \$500, generally, upon the defendants on the other counts, but suspended the latter fine for 3 years.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2103. Adulteration of amphetamine sulfate tablets. U. S. v. 576 Bottles and 1 Drum * * *. (F. D. C. No. 22375. Sample No. 52302-H.)

LIBEL FILED: January 17, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about August 31, 1946, by the Penn Lee Products, from St. Paul, Minn.

PRODUCT: 576 1,000-tablet bottles of *amphetamine sulfate tablets* and 1 unlabeled drum containing broken tablets of the same article removed from the labeled bottles, at St. Paul, Minn.

LABEL, IN PART: (Bottles) "Amphetamine Sulfate Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), desoxyephedrine hydrochloride had been substituted for amphetamine sulfate in the article.

DISPOSITION: March 27, 1947. No claimant having appeared, judgment was entered ordering the product destroyed.

2104. Adulteration of poke root and skullcap herb. U. S. v. 21 Bags, etc. (F. D. C. No. 19422. Sample Nos. 8617-H, 8618-H.)

LIBEL FILED: March 14, 1946, District of New Jersey.

ALLEGED SHIPMENT: On or about January 30, 1946, by the St. Louis Commission Co., from St. Louis, Mo.

PRODUCT: 21 bags containing approximately 1,535 pounds of *poke root* and 3 bales containing approximately 746 pounds of *skullcap herb* at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of rodent hair fragments, insects, and insect fragments.

DISPOSITION: April 29, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2105. Alleged adulteration and misbranding of Hormo-Fen Capsules and alleged misbranding of Hormo-Gen Capsules. U. S. v. Harlow B. Boyle and Charles E. Boyle (Boyle & Co.). Pleas of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 20190. Sample Nos. 28653-H, 32251-H.)

INFORMATION FILED: October 15, 1946, Southern District of California, against Harlow B. Boyle and Charles E. Boyle, partners, trading as Boyle & Co., Los Angeles, Calif.

*See also No. 2101.